Patient Information Leaflet for BIO CIMETIDINE 200 & 400

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BIO CIMETIDINE 200 film-coated tablets

BIO CIMETIDINE 400 film-coated tablets

Cimetidine

Sugar free

Read all of this leaflet carefully before you are given BIO CIMETIDINE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BIO CIMETIDINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BIO CIMETIDINE is and what it is used for
2. What you need to know before you take BIO CIMETIDINE
3. How to take BIO CIMETIDINE
4. Possible side effects
5. How to store BIO CIMETIDINE
6. Contents of the pack and other information.

1. What BIO CIMETIDINE is and what it is used for

BIO CIMETIDINE is an antacid and is used for the treatment of duodenal and benign gastric

ulceration (ulcers in the first part of the small intestine and in the stomach) and peptic oesophagitis, recurrent ulceration, stomal ulceration (ulceration near the opening between the stomach and the small intestine) and other conditions where reduction of gastric acid secretion has been shown to be beneficial as well as maintenance therapy for periods of up to one year in those patients with recurrence of duodenal ulceration after short-term therapy.

BIO CIMETIDINE is indicated in the management of those patients who are at high risk for bleeding of the upper gastrointestinal tract due to liver failure and treatment with medicines which lowers the body's resistance to disease, following kidney transplant. Management of pathological hypersecretion such as Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas and erosive gastro-oesophageal reflux disease (GORD).

2. What you need to know before you take BIO CIMETIDINE

Do not take BIO CIMETIDINE:

- If you are hypersensitive (allergic) to cimetidine or any of the other ingredients of BIO CIMETIDINE (listed in section 6).
- If you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).

Warnings and precautions

Tell your doctor if any of the following applies to you:

- If you have reduced renal function.
- If you are a middle-aged or elderly person, with new or recently changed indigestion symptoms (e.g. stomach pain or discomfort, heartburn).
- If you have a history of peptic ulcer, or if you are taking a non-steroidal anti-inflammatory medicine (NSAID) e.g. aspirin, ibuprofen, naproxen, diclofenac.
- If you are taking medicines, or you have an illness, that could cause a fall in blood cell count.

Children and adolescents

The use of BIO CIMETIDINE in children cannot be recommended as safety and/or efficacy has not been established.

Other medicines and BIO CIMETIDINE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Immunodepressants (ciclosporin).
- Heart medicines (e.g. nifedipine, diltiazem, lidocaine (lignocaine), metoprolol, procainamide).
- Anticonvulsants, to prevent fits (e.g. phenytoin).
- Suxamethonium (used for relaxing the muscle).
- Bronchodilators for breathing difficulties (e.g. theophylline).
- Antidepressants (e.g. amitriptyline).
- Antidiabetics (lowers glucose levels in the blood) (e.g. glipizide or metformin).
- Antifungals (used to treat fungal infections) (e.g. ketoconazole, itraconazole or posaconazole).
- Anti-cancer medicines (treatment of cancer or tumour) (e.g. carmustine, fluorouracil, epirubicin, or therapies such as radiation).
- Strong pain killers (e.g. morphine).
- Tacrolimus for the prevention of rejection following organ transplant.
- Antiretroviral medicines (used to treat human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS)) (e.g. atazanavir).
- Anticoagulants to thin your blood (e.g. warfarin).

When administered with BIO CIMETIDINE, a reduction in the dosage of these medicines may be needed. If concurrent administration of warfarin and BIO CIMETIDINE is necessary, your doctor will closely monitor the prothrombin time (the time taken for blood clotting to occur).

BIO CIMETIDINE with food and drink alcohol

See section 3.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BIO CIMETIDINE.

Safety and efficacy in pregnancy and breastfeeding have not been established.

You should not take BIO CIMETIDINE if you are pregnant or breastfeeding your baby.

Driving and using machines

Confusion, headache and dizziness have been reported with BIO CIMETIDINE. You should not drive or use machines until you know how BIO CIMETIDINE affects your ability to do so safely.

BIO CIMETIDINE contains sodium

BIO CIMETIDINE contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially sodium free.

3. How to take BIO CIMETIDINE

Do not share medicines prescribed for you with any other person.

Always take BIO CIMETIDINE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

BIO CIMETIDINE may be given by mouth or the nasogastric (passed through the nose into the stomach) route, and the total daily dose should not exceed 2,4 g. When BIO CIMETIDINE is given orally, the daytime doses should be taken with meals.

Duodenal and gastric ulcers

A single dose of 800 mg daily taken at bedtime, for 4 weeks in the case of a duodenal ulcer and 6 weeks for a gastric ulcer. Where appropriate, a maintenance dose of 400 mg at bedtime or 200 mg twice daily should be taken for a period up to a year.

Oesophageal reflux

A dose of 400 mg four times daily (with meals and at bedtime) for 4 – 8 weeks is recommended.

Zollinger-Ellison syndrome

A dose of 400 mg four times daily (with meals and at bedtime) for 4-8 weeks is recommended. This dose can be increased to a maximum of 2,4 g per day, if necessary.

Maintenance treatment: Prophylaxis of recurrent ulcer

400 mg at bedtime or increase to 400 mg twice a day, if necessary for up to one year.

Your doctor will tell you how long your treatment with BIO CIMETIDINE will last.

If you have the impression that the effect of BIO CIMETIDINE is too strong or too weak, tell your doctor or pharmacist.

If you take more BIO CIMETIDINE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BIO CIMETIDINE

If you have forgotten to take a dose, leave out that dose completely if it is almost time for your next dose. Take your next dose at the normal time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIO CIMETIDINE can have side effects.

Not all side effects reported for BIO CIMETIDINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO CIMETIDINE, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking BIO CIMETIDINE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIO CIMETIDINE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes (also called jaundice), and dark coloured urine.
- A rare type of anaemia in which the red and white blood cells and platelets are all reduced in number (symptoms might include tiredness, being short of breath, looking pale, frequent infections, bruising more easily or nose bleeds).
- Increase in heart rate.
- Slow or irregular heartbeat.
- Kidney problems (symptoms may include changes in the amount of urine passed and its colour, nausea, vomiting, confusion, fever and rash).
- Inflammation of the pancreas (sudden onset of abdominal pain, nausea and vomiting).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Aching muscles.
- Tiredness.
- Diarrhoea.
- Headache.
- Dizziness.

Less frequent side effects:

- Hair loss.
- Redness of the skin because of contact with irritating substance.
- Joint pain.
- Fever.
- Confusion.
- Trouble getting or keeping an erection (impotence).
- Breast enlargement in men.
- Nipple discharge.
- Feelings of sadness, depression.
- Hallucinations – seeing/feeling/hearing things that are not there.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of BIO CIMETIDINE.

5. How to store BIO CIMETIDINE

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C, protected from light.
- Do not store in bathrooms.
- Do not use after the expiry date stated on the label and carton.
- Take any expired medicine or medicine not used to your closest pharmacy for destruction.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIO CIMETIDINE contains

The active substance is cimetidine 200 mg per film-coated tablet or cimetidine 400 mg per film-coated tablet.

The other ingredients are colloidal silicone dioxide (Aerosil 200), corn starch/maize starch (Super Sonic), magnesium stearate, microcrystalline cellulose (Arbocel type A 300), Opadry 03F58792 White (consisting of HPMC 2910/hypromellose (E464), macrogol/PEG (E1521) and titanium dioxide (E171)), povidone K25 (Plasodone K-25), sodium lauryl sulphate (Vinapol-90P), sodium starch glycolate (Primojel), purified talcum.

What BIO CIMETIDINE looks like and contents of the pack

BIO CIMETIDINE 200 tablets are white, biconvex round film-coated tablets.

BIO CIMETIDINE 400 tablets are white bar-shaped biconvex film-coated tablets.

BIO CIMETIDINE tablets are available in:

BLISTER PACKS (10 tablets per strip)

Blister strips with clear, colourless polyvinylchloride (PVC) moulded to accept one tablet per pocket and sealed with soft, matte, silver, printed aluminium foil. Strips are packed into cartons with a patient information leaflet.

BIO CIMETIDINE 200 pack sizes: 60 and 150 tablets.

BIO CIMETIDINE 400 pack sizes: 60 tablets.

SECURITAINERS

Securitainer (polypropylene) containing tablets and patient information leaflet. Sealed with a securitainer snap-on cap (polyethylene) and labelled with a glossy adhesive printed label.

BIO CIMETIDINE 200 pack sizes: 60 and 150 tablets.

BIO CIMETIDINE 400 pack sizes: 60 and 500 tablets.

HDPE CONTAINERS

HDPE containers containing tablets and patient information leaflet. 100 cc white opaque HDPE container with white opaque screw cap and induction sealing wad.

BIO CIMETIDINE 200 pack sizes: 60 and 150 tablets.

BIO CIMETIDINE 400 pack sizes: 60 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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